

## UNITED STATES PATENT AND TRADEMARK OFFICE

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THE LAW OFFICE OF JILL L. WOODBURN, L.L.C.			LNAMENT R	
JILL L. WOODBURN 128 SHORE DR. OGDEN DUNES, IN 46368		GITOMER, RALPH J		
			ARTUNI	PAPER NUMBER
			775 DATE MAILED 03-31-2003	70

Please find below and/or attached an Office communication concerning this application or proceeding.

## Application No.

Applicant(s)

09/620,038

Examiner

Office Action Summary

Ralph Gitomer

Art Unit **1651** 

Hoss et al.



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) X. Responsive to communication(s) filed on Jan 2, 2003 2a) This action is **FINAL**. 2b) X This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) X Claim(s) 23-50 and 68-79 is/are pending in the application. 4a) Of the above, claim(s) \_\_\_\_\_\_ is/are withdrawn from consideration. is/are allowed. 5) Claim(s) 6) X Claim(s) 23-50 and 68-79 is/are rejected. is/are objected to. 7) : Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Claims 8) \_\_\_ Application Papers The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some\* c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \*See the attached detailed Office action for a list of the certified copies not received. 14). Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 4) Interview Summary (PTO-413) Paper No(s). 1) Notice of References Cited (PTO-892) 5) \_\_ Notice of Informal Patent Application (PTO-152) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s).

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The RCE request received 1/2/03 and the amendment received 11/14/02 have been entered and claims 23-50, 68-79 are currently pending in this application.

The rejection under 35 USC 103 over Pfeiffer (6,091,976) is maintained.

Applicant's arguments filed 11/14/02 have been fully considered but they are not persuasive.

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Applicants argue that Pfeiffer teaches setting an initial glucose concentration in the perfusion solution which is maintained unchanged during testing. The predetermined glucose baseline is set in other words. Whereas the presently claimed invention includes adjusting the starting content of glucose in the perfusate in accordance with a command variable corresponding with the glucose concentration of the body fluid.

It is the examiner's position that ss presently claimed, this point of novelty feature is so vague as to not be possible to distinguish from Pfeiffer. Pfeiffer teaches in the abstract, continuously detected signals for monitoring tissue glucose concentrations. The predetermined concentration is set within the physiological range depending on the tissue glucose concentration as described in column 1 last paragraph. The function of the teaching of Pfeiffer and that presently claimed appears identical. See the present specification page 2 last full paragraph.

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Claims 23-50, 68-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 23 line 8, the measuring cell lacks antecedent basis. In claim 23 the obtaining measurement signals does not state how the signals are obtained nor from what. And the next step, measuring the measurement signals is not understood. There are no steps presented to accomplish the last determining step. Claim 23 as amended still does not have a step which determines glucose concentration. Note there may be some confusion between content and concentration in the claims. The determining of the starting content of glucose in claims 25 and 26 remains indefinite.

Regarding new claims 68-79, in claim 68 in alternating successive transport and dialysis intervals in not understood. Further, measuring measurement signals is unclear because no measurement signals have been obtained and what they might be measured for is not seen. And how can one adjust the starting content of glucose if one must first measure the glucose concentration? If the starting content of glucose is set according to a command of some sort, how can the momentary starting content of glucose be a measure of glucose content of the body fluid? If a feedback is intended to adjust the starting

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glucose concentration, it is not found in the claims as presented. Claim 76 contains many values but how they are obtained is not found in the claims.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at

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Ralph Gitomer Primary Examiner Group 1651

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